IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

LORI ENGLISH and GREGORY ENGLISH,	:	**CIVIL ACTION NO. 1:21-CV-923**
	:	
	:	**(Judge Conner)**
Plaintiff	:	
	:	
v.	:	
	:	
EISAI, INC., and ARENA PHARMACEUTICALS, INC.,	:	
	:	
	:	
Defendants	:	

MEMORANDUM

Plaintiffs commenced this personal injury lawsuit asserting various state-law claims against defendants Eisai, Inc., and Arena Pharmaceuticals, Inc.[1] Their claims arise from plaintiff Lori English's use of prescription weight-loss medication Belviq. Defendants move the court to partially dismiss plaintiffs' complaint. The court will grant in part and deny in part defendants' motions.

I. Factual Background & Procedural History

Belviq is the brand name for lorcaserin hydrochloride, a prescription weight-loss medication intended to be used "as an adjunct to reduced-calorie diet and increased physical activity for chronic weight management." (See Doc. 1 ¶¶ 2, 43). Plaintiffs allege defendants Eisai, Inc. ("Eisai"), and Arena Pharmaceuticals, Inc. ("Arena"), were involved in researching, developing, selling, and marketing

[1] Plaintiffs initially named Eisai's parent holding corporations, Eisai Co., Ltd., and Arena's subsidiary, Arena Pharmaceuticals GmbH, as defendants in this lawsuit. (See Doc. 1 ¶¶ 26, 32, 37). Plaintiffs have voluntarily dismissed both Eisai Co., Ltd., and Arena Pharmaceuticals GmbH. (See Docs. 31, 32).

Belviq. (See id. ¶¶ 4, 21, 37). The complaint describes Belviq as "a first-in-class oral selective serotonin 5HT2c receptor agonist" available in 10 milligram tablets to be taken twice daily or 20 milligram extended-release tablets to be taken once daily. (See id. ¶ 60). The United States Food and Drug Administration ("FDA") approved Belviq for marketing and sale in the United States in June 2012, later approving the extended-release version of the drug in July 2016. (See id. ¶¶ 45, 52).

On January 14, 2020, the FDA issued a safety communication regarding Belviq, warning certain clinical trial results demonstrated a possible increased risk of cancer. (See id. ¶ 86). The FDA's communication indicated its evaluation of the potential risks attributable to Belviq was ongoing and a "causal association was at that time uncertain." (See id.) On February 13, 2020, the FDA announced that Eisai had voluntarily withdrawn Belviq from the market. (See id. ¶ 87). The FDA reported that analysis of post-marketing trial data had indicated "an imbalance of cancer in patients taking Belviq that increased with treatment duration, including pancreatic, colorectal, and lung cancer." (See id.) The FDA concluded Belviq's risks outweighed its benefits and recommended that patients cease taking Belviq. (See id.) The FDA further instructed health care professionals to stop prescribing Belviq and to contact their patients, inform them of the increased risk of cancer, and ask them to stop taking Belviq. (See id.)

Plaintiff Lori English ("English") was prescribed Belviq by her primary care physician in January 2015. (See id. ¶ 15). English continued taking Belviq through approximately June 2020. (See id.) In March 2016, while taking Belviq, English was diagnosed with breast cancer. (See id. ¶ 17). After learning of Belviq's

withdrawal from the market, plaintiffs commenced the instant lawsuit alleging English's use of Belviq caused her breast cancer. (See id.) Plaintiffs contend that defendants knew or should have known of Belviq's carcinogenicity based on earlier trials and testing and that defendants failed to warn consumers and health care providers of those known risks. (See generally id. ¶¶ 101-137, 142-177, 182-220, 226-251, 256-316, 321-347).

Plaintiffs assert seven Pennsylvania state-law causes of action against defendants: negligence (Count 1); strict products liability – defective design and failure to warn (Count 2); breach of express warranty (Count 3); breach of implied warranty (Count 4); fraudulent misrepresentation and concealment (Count 5); and negligent misrepresentation (Count 6); as well as a claim for loss of consortium on behalf of English's husband, Gregory English (Count 7). Defendants filed motions to partially dismiss plaintiff's complaint pursuant to Federal Rule of Civil Procedure 12(b)(6). The motions are fully briefed and ripe for disposition.

II. Legal Standard

Rule 12(b)(6) of the Federal Rules of Civil Procedure provides for the dismissal of complaints that fail to state a claim upon which relief may be granted. FED. R. CIV. P. 12(b)(6). When ruling on a motion to dismiss under Rule 12(b)(6), the court must "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." Phillips v. County of Allegheny, 515 F.3d 224, 233 (3d Cir. 2008) (quoting Pinker v. Roche Holdings, Ltd., 292 F.3d 361, 374 n.7 (3d Cir. 2002)).

Federal notice and pleading rules require the complaint to provide "the defendant fair notice of what the . . . claim is and the grounds upon which it rests." Phillips, 515 F.3d at 232 (alteration in original) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007)). To test the sufficiency of the complaint, the court conducts a three-step inquiry. See Santiago v. Warminster Township, 629 F.3d 121, 130-31 (3d Cir. 2010). In the first step, "the court must 'tak[e] note of the elements a plaintiff must plead to state a claim.'" Id. at 130 (alteration in original) (quoting Ashcroft v. Iqbal, 556 U.S. 662, 675 (2009)). Next, the factual and legal elements of a claim must be separated; well-pleaded facts are accepted as true, while mere legal conclusions may be disregarded. Id. at 131-32; see Fowler v. UPMC Shadyside, 578 F.3d 203, 210-11 (3d Cir. 2009). Once the court isolates the well-pleaded factual allegations, it must determine whether they are sufficient to show a "plausible claim for relief." Iqbal, 556 U.S. at 679 (citing Twombly, 550 U.S. at 556); Twombly, 550 U.S. at 556. A claim is facially plausible when the plaintiff pleads facts "that allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Iqbal, 556 U.S. at 678.

III. Discussion

Defendants move to dismiss all of plaintiffs' claims except the negligent failure-to-warn claim in Count 1 and the derivative loss-of-consortium claim in Count 7. In response to defendants' motions, plaintiffs elected to withdraw the strict-liability claims in Count 2 and the implied-warranty claim in Count 4. (See Doc. 23 at 3). We construe plaintiffs' response as a notice of voluntary dismissal of Counts 2 and 4 and will accordingly dismiss both counts. See FED. R. CIV. P.

41(a)(1)(A)(i). We address defendants' arguments as to the remaining claims *seriatim*.[2]

A. Defective Design[3]

Defendants seek to dismiss plaintiffs' defective-design claim on the ground that it is based on nothing more than "conclusory allegations" of a design defect. (See Doc. 17 at 5; see also Doc. 15 at 1). When, as here, a plaintiff premises their design-defect claim on the theory that a better alternative was available, they must allege, *inter alia*, "an alternative, feasible, safer design [that] would have lessened or eliminated the injury plaintiff suffered." See Berrier v. Simplicity Mfg., Inc., 563 F.3d 38, 64 (3d Cir. 2009) (quoting Habecker v. Clark Equip. Co., 36 F.3d 278, 281 (3d Cir. 1994)) (emphasis omitted); see also Lance v. Wyeth, 85 A.3d 434, 458 n.36 (Pa. 2014) (citing Duchess v. Langston Corp., 769 A.2d 1131, 1149 n.24 (Pa. 2001)). To meet this requirement, a plaintiff must do more than "baldly stat[e] that there are

[2] Arena's supporting brief incorporates all arguments raised in Eisai's supporting brief, raising just one argument independent of Eisai. (See Doc. 15). Based on this incorporation, we refer to the arguments raised by Eisai as having been raised by both defendants.

[3] Defendants initially interpreted Count 1 as stating only two theories of negligence liability: defective design and failure to warn. (See Doc. 17 at 1-2 & n.1; see also Doc. 15 at 1 & n.1). In their opposition brief, plaintiffs contend that Count 1 actually comprises three claims: defective design, failure to warn, and failure to test. (See Doc. 23 at 3). As defendants accurately observe, Pennsylvania courts do not recognize a freestanding failure-to-test claim. See Barton v. Lowe's Home Ctrs., Inc., 124 A.3d 349, 358-59 (Pa. Super. Ct. 2015) (citing Viguers v. Philip Morris USA, Inc., 837 A.2d 534, 541 (Pa. Super. Ct. 2003), aff'd, 881 A.2d 1262 (Pa. 2005) (*per curiam*)); see also Houtz v. Encore Med. Corp., No. 4:14-CV-536, 2014 WL 6982767, at *3 (M.D. Pa. Dec. 10, 2014) (same); Salvio v. Amgen, Inc., 810 F. Supp. 2d 745, 751 (E.D. Pa. Aug. 2011) (citing Viguers, 837 A.2d at 541; Wolfe v. McNeil-PPC, Inc., 773 F. Supp. 2d 561, 570 (E.D. Pa. 2011)). We will thus dismiss Count 1 to the extent it is premised on a failure-to-test theory.

safer alternatives"; they must provide factual support demonstrating those alternatives exist. See Salvio, 810 F. Supp. 2d at 754 (citation omitted); see also McGrain v. C.R. Bard, Inc., No. 21-1539, ___ F. Supp. 3d ___, 2021 WL 3288601, at *8 (E.D. Pa. July 30, 2021) (dismissing defective-design claim in medical-device case when plaintiff did not allege "safer, feasible alternatives in any level of meaningful detail").

Plaintiffs allege Belviq was unreasonably dangerous because an alternative, feasible, safer design exists, (see Doc. 1 ¶ 108); they allege what that alternative, feasible, safer design is—a "pharmaceutical drug that [does] not affect the serotonin pathway," (see id. ¶ 110); and they allege not only that the alternative design exists, but that it exists "in the exclusive possession, custody[,] and control of Defendants," (see id. ¶ 108). This case stands in stark contrast to those cited by defendants in which defective-design claims were dismissed as too conclusory. Cf., e.g., Salvio, 810 F. Supp. 2d at 754 (dismissing defective-design claim when only allegation of alternative design was conclusory statement that plaintiff's decedent "would have used another treatment regimen that was safer"). We reject defendants' contention that plaintiffs' complaint cannot survive Rule 12(b)(6) scrutiny.

Defendants also contend that plaintiffs' claim must be dismissed to the extent their proffered alternative design exists only "in the form of some unspecified, new or different formulation or molecule." (See Doc. 17 at 6). Accepting the complaint's allegations as true, the proffered alternative design is not hypothetical—plaintiffs allege it exists and is in defendants' possession. (See Doc. 1 ¶ 108). Nor is this a case, like those cited by defendants, in which the plaintiff simply lists alternative

products, as opposed to alternative designs *for* a product. Cf. Bell v. Boehringer Ingelheim Pharms., Inc., No. 17-1153, 2018 WL 2447788, at *5 (W.D. Pa. May 13, 2018) (dismissing defective-design claim when plaintiff "merely listed completely different drugs that he could have taken"); Salvio v. Amgen Inc., No. 2:11-CV-553, 2012 WL 517446, at *7 (W.D. Pa. Feb. 15, 2012) (same when plaintiff "failed to allege any alternative ways in which [drug] could have been designed" and "merely list[ed] completely different drugs that Decedent could have taken"). Whether the alternative design proffered by plaintiffs is so different as to be "an altogether essentially different product," (see Doc. 33 at 4 (quoting Salvio, 2012 WL 517446, at *7)), is a highly factual inquiry better suited for resolution on a fully developed record.

Plaintiffs have satisfied their burden of pleading an alternative, feasible, safer design. We will thus deny defendants' motions to dismiss plaintiffs' defective-design claim on this ground, without prejudice to defendants' right to reassert the issue at the Rule 56 stage.

B. Remaining Claims

Defendants argue that plaintiffs' claims for breach of express warranty, fraudulent misrepresentation and concealment, and negligent misrepresentation must be dismissed as incognizable under Pennsylvania law. Defendants ground their argument in the Pennsylvania Supreme Court's decision in Hahn v. Richter, 673 A.2d 888 (Pa. 1996). The court in Hahn rejected strict liability as a basis for recovery in suits against prescription-drug manufacturers premised upon alleged failure to provide sufficient warnings. See id. at 563. The court observed in closing

that "where the adequacy of warnings associated with prescription drugs is at issue, the failure of the manufacturer to exercise reasonable care to warn of dangers, *i.e.*, the manufacturer's negligence, is the only recognized basis of liability." See id.

We turn first to defendants' argument as to plaintiffs' express-warranty claim. Defendants cite to a handful of district court cases—Rowland v. Novartis Pharmaceuticals Corp., 34 F. Supp. 3d 556, 569 (W.D. Pa. 2014), Salvio v. Amgen, Inc., 810 F. Supp. 2d 745, 756 (E.D. Pa. 2011), and Doughtery v. C.R. Bard, No. 11-6048, 2012 WL 2940727, at *8 (E.D. Pa. July 18, 2012)—to support their assertion that Hahn precludes *all* non-negligence claims, including express warranty claims, against prescription drug manufacturers. (See Doc. 17 at 8). We note as an initial matter that one of the cited cases, Dougherty, actually held the opposite: the court differentiated between tort-based claims (the strict liability and negligence claims at issue in Hahn) and contract-based claims (like one for breach of express warranty) and concluded that "Pennsylvania law does *not* preclude express-warranty claims against manufacturers of prescription drugs and devices." See Doughtery, 2012 WL 2940727, at *8-9 (emphasis added). The Doughtery court's reasoning remains the minority view, see, e.g., Bell, 2018 WL 928237, at *3; Rowland, 34 F. Supp. 3d at 569 (colleting cases); Salvio, 810 F. Supp. 2d at 755-56 (same), but has garnered some support, see, e.g., Shelley v. Ethicon, No. 12-6862, 2013 WL 3463505, at *3 (E.D. Pa. July 10, 2013) (holding Hahn precludes implied-warranty claims but not express-warranty claims, since the latter "enforce a contractual promise expressly and voluntarily made"); Kee v. Zimmer, Inc., 871 F. Supp. 2d 405, 409-10 & n.4 (E.D. Pa.

2012) (reviewing merits of express-warranty and fraud claims since reading Hahn to bar all non-negligence claims "takes Hahn beyond the scope of its holding").

Other than offering conclusory assertions and invoking a handful of district-court cases, defendants offer no meaningful argument favoring adoption of their position. Of particular interest is the fact that defendants did not cite to contrary authority in their initial brief and did not cite to any Pennsylvania state-court authority or policy, beyond Hahn, to support their view. Defendants also failed to engage with the countervailing authority once plaintiffs identified it, other than, once again, leaning in cursory fashion on Hahn. (See Doc. 33 at 5-6). Given the split of authority on this issue, as well as defendants' failure to develop their argument, we will not address their conclusory request to dismiss the express-warranty claim at this stage.[4] See, e.g., Crockett v. Luitpold Pharms., Inc., No. 19-276, 2020 WL 433367, at *5 (E.D. Pa. Jan. 28, 2020) (adopting same approach); (see

[4] Arena also moves the court to dismiss plaintiff's express warranty claim for the additional reason that Arena "never distributed or sold Belviq in the United States." (See Doc. 15 at 2). Arena cites as support for this assertion various Belviq product labels published on the FDA's website which state Belviq is a "registered trademark of" and "[m]anufactured by Arena Pharmaceuticals GmbH," a wholly owned subsidiary of Arena, but "[d]istributed by Eisai." See *Belviq Product Label*, https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/022529lbl.pdf (revised June 2012); *Belviq Product Label*, https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022529s003lbl.pdf (revised Dec. 2014); *Belviq Product Label*, https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/022529s005s007,208524s001lbl.pdf (revised May 2017). Arena asks the court to take judicial notice of these labels and dismiss plaintiffs' warranty claim against it on this basis. We decline to do so. Even if the court were to take judicial notice as requested, the complaint expressly alleges that Arena "is involved in the research, development, sales, and marketing of . . . Belviq and lorcaserin hydrochloride." (See Doc. 1 ¶ 37). We will not resolve this factual dispute at the Rule 12 stage. Accordingly, we will deny Arena's motion to dismiss on this additional ground.

also Doc. 40 ¶ 13 (warning counsel the court will summarily deny any motion for which supporting brief "offers only conclusory assertions or rationale")).

We likewise decline to dismiss plaintiffs' negligent misrepresentation claim, although for different reasons. Hahn plainly holds that claims sounding in negligence and premised on a failure-to-warn theory are viable against prescription drug manufacturers. See Hahn, 673 A.2d at 891. Defendants have not identified a single decision foreclosing a *negligent* misrepresentation claim under Hahn. (Cf. Doc. 17 at 10 (citing McLaughlin v. Bayer Corp., 172 F. Supp. 3d 804, 825-26 (E.D. Pa. 2016) (applying Hahn to fraudulent concealment claim but reviewing merits of negligent misrepresentation claim); Kester v. Zimmer Holdings, Inc., No. 2:10-CV-523, 2010 WL 4103553, at *4 (W.D. Pa. Oct. 18, 2010) (applying Hahn to fraudulent concealment claim); Kline v. Pfizer, Inc., No. 08-3238, 2009 WL 32477, at *2-4 (E.D. Pa. Jan. 6, 2009) (applying Hahn to claims for fraudulent misrepresentation and concealment but allowing negligent misrepresentation claim to proceed))). We hold that a negligent misrepresentation claim against a prescription drug manufacturer and premised on a failure-to-warn theory remains cognizable under Pennsylvania law. See, e.g., Leonard v. Taro Pharms. USA, Inc., No. 10cv1341, 2010 WL 4961647, at *5-6 (W.D. Pa. Dec. 2, 2010) (dismissing intentional misrepresentation claim but finding negligent misrepresentation claim viable under Hahn); Colacicco v. Apotex,

Inc., 432 F. Supp. 2d 514, 547-48 (E.D. Pa. 2006) (same with respect to fraudulent misrepresentation claim), vacated on other grounds, 556 U.S. 1101 (2009) (mem.).[5]

The same cannot be said for plaintiffs' fraudulent misrepresentation and concealment claims. Most district courts within our circuit have held that fraud-based claims premised on a prescription drug manufacturer's deficient warnings are barred by Hahn. See, e.g., Kline, 2009 WL 32477, at *2-4 (dismissing fraudulent misrepresentation and concealment claims in prescription-drug case since claims were "rooted in a theory of failure to warn"); see also Kester, 2010 WL 4103553, at *4 (dismissing fraudulent concealment claim in medical-device case when "very basis"

[5] Defendants also seek to dismiss plaintiffs' negligent misrepresentation claim for failure to plead the claim with particularly pursuant to Federal Rule of Civil Procedure 9(b). (See Doc. 17 at 12-13; Doc. 33 at 7-8). Rule 9(b) requires a plaintiff to plead "fraud or mistake" with "particularity." See FED. R. CIV. P. 9(b). Our court of appeals has made clear that this heightened pleading requirement applies to a claim which "sound[s] in fraud" even when "fraud is not a necessary element of" the claim. See *In re* Westinghouse Sec. Litig., 90 F.3d 696, 717 (3d Cir. 1996). The rule requires a plaintiff to "go well beyond Rule 8's threshold of plausibility" and articulate "all of the essential factual background that would accompany the first paragraph of any newspaper story—that is, the who, what, when, where, and how of the events at issue." United States *ex rel.* Bookwalter v. UPMC, 946 F.3d 162, 176 (3d Cir. 2019) (citation omitted). Assuming *arguendo* Rule 9(b) applies to plaintiffs' negligent misrepresentation claim, the complaint's allegations clear the particularity bar. Plaintiffs articulate who made the misrepresentative statements (defendants), what the statements were (that Belviq was safe and effective for use, its benefits outweighed its risk, and it had been adequately tested), when the statements were made (between 2015 and 2020), and where and how the statements were made (in television advertisements and on Belviq's product label). (See Doc. 1 ¶¶ 257, 259, 261, 263, 267-271, 279-283, 320, 327, 332-336). Contrary to defendants' assertion, Rule 9(b) does not require plaintiffs "to plead anything more, such as the date, time, place, or content of every single allegedly false . . . claim." See Bookwalter, 946 F.3d at 176. Plaintiffs' allegations place defendants on adequate "notice of the precise misconduct with which [they are] charged." See Alpizar-Fallas v. Favero, 908 F.3d 910, 919 (3d Cir. 2018) (quoting Frederico v. Home Depot, 507 F.3d 188, 200 (3d Cir. 2007)). We will thus deny defendants' motion to the extent it is grounded in Rule 9(b).

of claim was that defendants violated duty to disclose risks). Those courts to have allowed fraud claims to proceed despite Hahn have generally done so on the theory that the allegations in the particular case "go beyond a mere failure to warn." See, e.g., Cutruzzula v. Bayer Healthcare Pharms. Inc., No. 14-1474, 2015 WL 8488670, at *5 (W.D. Pa. Nov. 17, 2015) (permitting fraud claims to proceed when plaintiff alleged defendant made affirmative factual misrepresentations about prescription drug).

Plaintiffs' fraud claims are grounded entirely in their allegations that defendants knew or should have known Belviq was dangerous but concealed that knowledge and misrepresented their product as safe—quintessentially, that they failed to warn of Belviq's known dangers. (See, e.g., Doc. 1 ¶¶ 256-263, 269-274, 280-290). Plaintiffs allege that English would not have taken Belviq had she been properly warned about its risks, (see id. ¶¶ 293-300), and that defendants breached "their duties to disclose Belviq's serious safety risks and lack of efficacy" to the public, (see id. ¶ 310). Plaintiffs' fraudulent concealment and misrepresentation claims are thus indistinguishable from and do not extend beyond their negligent failure-to-warn claim. Cf. Cutruzzula, 2015 WL 8488670, at *5. Under Pennsylvania law, plaintiffs are restricted to negligence claims in pursuing their failure-to-warn theory. See Hahn, 673 A.2d at 891. We will therefore grant defendants' motion to dismiss plaintiffs' fraudulent misrepresentation and concealment claims.

C. Leave to Amend

Plaintiffs request leave to amend their complaint to the extent the court finds any portion thereof to be deficient. (See Doc. 23 at 20). Curative amendment

is conceivable if plaintiffs are able to allege facts which demonstrate defendants made affirmative factual misrepresentations about Belviq that "go beyond a mere failure to warn." See Cutruzzula, 2015 WL 848670, at *5. Accordingly, mindful that leave to amend should be liberally granted, see FED. R. CIV. P. 15(a), we will grant leave to amend as to the fraudulent concealment and misrepresentation count only.

IV. Conclusion

We will grant in part and deny in part defendants' motions to dismiss. An appropriate order shall issue.

/S/ CHRISTOPHER C. CONNER
Christopher C. Conner
United States District Judge
Middle District of Pennsylvania

Dated: March 14, 2022